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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,504	10/18/2000	Marc K. Wallack	11221/5	5100

26646 7590 08/27/2002

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/27/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

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Response to Amendment

The reply filed on 6/6/02 is not fully responsive to the prior Office action because of the following omission(s) or matter(s): while the applicant has elected with traverse the subject matter of group II, claims 18-38, and 55-107, for prosecution on the merits, the applicant has failed to elect a species of first immunostimulatory molecule and a species of second immunostimulatory molecule for group II from the list of a)-al) as required in the restriction/election requirement mailed on 3/26/02, paper no. 10. The relevant paragraph taken from the previous Office action can be found in bold lettering on page 6 of this communication. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

The original restriction requirement as mailed on 3/26/02 is presented below for applicant's convenience.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1-17 and 54, drawn to antigen presenting cells infected with a vaccinia virus encoding an immunostimulatory molecule and methods of using said cells, classified in classes 435 and 424 , subclasses 325 and 93.2 respectively .
- II. Claims 18-38 and 55-107, drawn to composition of vaccinia virus encoding a first immunostimulatory molecule and cells infected with a vaccinia virus encoding a second immunostimulatory molecule, and methods of using said composition, classified in classes 435 and 514, subclasses 320.1, 325 and 44.
- III. Claims 1-17 and 39-53, drawn to antigen presenting cells infected with a vaccinia virus encoding an immunostimulatory molecule and methods of making said cells, classified in class 435, subclasses 320.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

- 1) Inventions I and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).
- 2) Inventions I and III are distinct from invention II in that invention II includes a second independent vaccinia virus which encodes a different immunostimulatory molecule from that encoded by the vaccinia virus used to infect the antigen presenting cells. Further, the methods of immunizing using the compositions of invention II are substantially different from those of invention I in that invention II requires the direct administration of a vaccinia virus to a mammal.

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As such the methods utilize different substantially different reagents with substantially different biological functions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of immunostimulatory molecules of the claimed invention:

- a) IL-2
- b) IL-3
- c) IL-4
- d) IL-6
- e) IL-7
- f) IL-12
- g) IL-15
- h) IL-18
- I) FLT-3/FLK-2 ligand
- j) FLT-3 ligand
- k) GM-CSF
- l) G-CSF

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m) stem cell factor

n) interferon

o) MAGE-1

p) MAGE-3

q) GAGE

r) BAGE

s) PRAME

t) NY-ESO-1

u) tyrosinase

v) Melan-A

w) MART-1

x) gp100

y) TRP-1

z) TRP-2

aa) MUM-1

ab) CDK4

ac) beta-catenin

ad) gp100in4

ae) p15

af) N-acetylglucosaminyltransferase

ag) B7-1

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ah) TA-90

ai) lysosome-associate membrane protein

aj) melanocyte-stimulating hormone receptor

ak) p90

al) calnexin

Please note that the species identified above represent proteins with vastly different physical characteristics and biological properties.

If invention I or invention III is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of immunomodulatory molecule from the group a)-al) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims 1-4, 8-17 and 39-54 are generic.

If invention II is elected, Applicant is further required under 35 U.S.C. 121 to elect a first disclosed species from the group a)-al) for the first immunostimulatory molecule and a second disclosed species from the group a)-al) for the second immunostimulatory molecule. Claims 18-22, 28-38, 55-63, 70-95, and 102-107 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The

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technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

A handwritten signature in black ink, appearing to read 'AM Wehbé', with a stylized flourish at the end.

ANNE M. WEHBÉ PH.D
PRIMARY EXAMINER